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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,376	10/11/2001	Chad A. Mirkin	00-713-i12	9821

7590

09/19/2002

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EXAMINER

HASHEMI, SHAR S

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 09/19/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,376

Applicant(s)

MIRKIN ET AL.

Examiner

Shar Hashemi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/11/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 237-265 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 237-265 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed on 2/19/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

2. The disclosure is objected to because the following serial numbers must be updated: 09/344, 667 (page 1, line 8), 09/240, 755 (page 1, line 10), PCT/US97/12783 (page 1, line 11),
Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 237-265 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 237-265 are indefinite because the limitations in claims 237, 243 and 253 are unclear. The claims recite the limitations of the compositions in passive language. It is

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recommended to rewrite the claims to recite the limitations of the compositions in **active** language (e.g. nanoparticle-oligonucleotide conjugates comprising attaching oligonucleotides to the nanoparticles...).

B) Claim 252 is indefinite because the limitation "the method" is unclear because the claim depends on a product claim. There is insufficient antecedent basis for this limitation in the claim.

C) Claim 244 is indefinite because the limitation "it" is unclear. It is unclear as to whether the term "it" refers to the spacer portion of the nanoparticle or the spacer portion of the recognition oligonucleotide.

D) Claim 244 is indefinite because the term "spacer portion" is unclear. It is unclear as to whether the term "spacer portion" refers to the recognition oligonucleotide or the nanoparticle.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 237, 241-243, 251-253 & 264-265 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3 & 4 of U.S.

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Patent No.6, 417, 340 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 3 & 4 of U.S. Patent No.6, 417, 340 B1 are drawn to a similar nanoparticle-oligonucleotide conjugate.

Claims 1, 3 & 4 of U.S. Patent No.6, 417, 340 B1 are drawn to nanoparticle-oligonucleotide conjugates that comprise oligonucleotides attached to nanoparticles, oligonucleotides residing on the surface of the nanoparticles have a surface density that ensures stability of the nanoparticle-oligonucleotide conjugates, oligonucleotides having one type of recognition oligonucleotide and one type of diluent oligonucleotide, where the recognition oligonucleotide contains a spacer portion and a recognition portion, where the spacer portion is bound to the nanoparticles, where the recognition portion has a sequence that is complementary to a portion of a nucleic acid. Claims are drawn to the further limitation of metal nanoparticles that are gold.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C.

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122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 237-265 are rejected under 35 U.S.C. 102(e) as being anticipated by Mirkin et al (US 6, 417, 340 B1 July 9, 2002).

Mirkin et al in US 6, 417, 340 B1 teach nanoparticle-oligonucleotide conjugates that comprise oligonucleotides attached to nanoparticles, oligonucleotides residing on the surface of the nanoparticles have a surface density that ensures stability of the nanoparticle-oligonucleotide conjugates, oligonucleotides having one type of recognition oligonucleotide and one type of diluent oligonucleotide, where the recognition oligonucleotide contains a spacer portion and a recognition portion, where the spacer portion is bound to the nanoparticles, where the recognition portion has a sequence that is complementary to a portion of a nucleic acid (see whole document, especially col. 21, lines 45-67; col. 22, lines 1-63). They further teach metal nanoparticles that contain gold (col. 16, lines 30-67).

They further teach that the spacer portion of the recognition oligonucleotide is covalently bound to a moiety, where the moiety contains a functional group that allows the spacer portion to bind to the nanoparticles (col. 29, lines 1-67). They teach the spacer portion contains ten to thirty nucleotides (col. 49, lines 15-54). They also teach the diluent oligonucleotide and the spacer portion of the recognition oligonucleotide share the same sequence and the same number of nucleotides (col. 49, lines 22-54). They teach the nucleotide bases of the spacer portion contain all cytosines (col. 52, lines 49-65).

They further teach that the surface density of the oligonucleotides residing on the surface of the nanoparticles is greater than or equal to 10 picomoles/cm² (col. 51, lines 20-67). They also teach that the surface density of the oligonucleotides residing on the surface of the nanoparticles is greater than or equal to 15 picomoles/cm². They also teach that the surface density of the oligonucleotides residing on the surface of the nanoparticles is between 15 picomoles/cm² to 40 picomoles/cm². (col. 52, lines 1-67).

7. Claims 237, 241-244, 251-255, & 264-265 are rejected under 35 U.S.C. 102(e) as being anticipated by Powell (US 5, 728, 590 March 17, 1998).

Powell in US 5, 728, 590 teaches nanoparticle-oligonucleotide conjugates that comprise oligonucleotides attached to nanoparticles, oligonucleotides residing on the surface of the nanoparticles have a surface density that ensures stability of the nanoparticle-oligonucleotide conjugates, oligonucleotides having one type of recognition oligonucleotide and one type of diluent oligonucleotide, where the recognition oligonucleotide contains a spacer portion and a recognition portion, where the spacer portion is bound to the nanoparticles, where the recognition portion has a sequence that is complementary to a portion of a nucleic acid (see whole document, especially col. 14-16, lines 1-67). He further teaches metal nanoparticles that contain gold (col. 14, lines 35-52).

He further teaches that the spacer portion of the recognition oligonucleotide is covalently bound to a moiety, where the moiety contains a functional group that allows the spacer portion to bind to the nanoparticles (col. 15, lines 1-24).

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8. Claims 237, 241-244, 251-255, & 264-265 are rejected under 35 U.S.C. 102(e) as being anticipated by Hainfeld et al (US 6, 121, 425 September 19, 2000).

Hainfeld et al in US 6, 121, 425 teaches nanoparticle-oligonucleotide conjugates that comprise oligonucleotides attached to nanoparticles, oligonucleotides residing on the surface of the nanoparticles have a surface density that ensures stability of the nanoparticle-oligonucleotide conjugates, oligonucleotides having one type of recognition oligonucleotide and one type of diluent oligonucleotide, where the recognition oligonucleotide contains a spacer portion and a recognition portion, where the spacer portion is bound to the nanoparticles, where the recognition portion has a sequence that is complementary to a portion of a nucleic acid (see whole document, especially col. 14-16, lines 1-67). They further teach metal nanoparticles that contain gold (col. 14, lines 35-52).

They further teach that the spacer portion of the recognition oligonucleotide is covalently bound to a moiety, where the moiety contains a functional group that allows the spacer portion to bind to the nanoparticles (col. 15, lines 1-24).

SUMMARY

9. No claims allowed.

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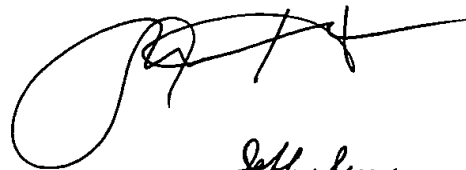
CONCLUSION

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840 and whose e-mail address is shar.hashemi@uspto.gov. However, the Office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can be best reached on weekdays from 7:00 a.m. to 3:30 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Sharon Thornton for Art Unit 1637 whose telephone number is (703)-305-3001.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-1235 and Before Final FAX (703) 872-9306 or After Final FAX (703) 308-9307.

September 5, 2002



JEFFREY SIEW
PRIMARY EXAMINER

9/12/02